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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,336	10/16/2003	John T. Kilcoyne	1065-012US05	7853
28863 7590 01/14/2008 SHUMAKER & SIEFFERT, P. A. 1625 RADIO DRIVE SUITE 300 WOODBURY, MN 55125			EXAMINER NGUYEN, HUONG Q	
			ART UNIT	PAPER NUMBER
			3736	
			NOTIFICATION DATE	DELIVERY MODE
			01/14/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@ssiplaw.com

Office Action Summary

Application No.

10/687,336

Applicant(s)

KILCOYNE ET AL.

Examiner

Helen Nguyen

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 50-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 50-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 12/5/2007.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

1. This Office Action is responsive to the amendment filed 9/27/2007. Claim 50 is amended. Claim 58 is new. The amendments to the specification are acknowledged rendering the previous objections to the specification moot. **Claims 50-58** remain pending.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 12/5/2007 is/are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. **Claims 50-55 and 58** are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman et al (US Pat No. 6088608) in view of Brune (US Pat No. 5984875), further in view of Ishikawa et al (US Pat No. 6398710) and Scarantino et al (US Pat No. 6402689).

5. In regard to **Claims 50 and 55**, Schulman et al disclose a system for measuring physiological parameters in the body of a patient, such as gastroesophageal reflux, the system comprising:

a plurality of sensors 10a-c etc. adapted to be implanted in the body of a patient (Col.3: 32-46), where each of the plurality of sensors periodically measures a physiological parameter indicative of gastroesophageal reflux such as pH (Col.4: 59-64) and wherein each of the plurality of sensors periodically transmits a signal indicative of the physiological that is indicative of a gastroesophageal reflux (Col.5: 16-23);

a receiver 16 that receives the signals from the plurality of sensors and records the signals.

6. However, Schulman et al do not disclose each signal transmitted by the plurality of sensors includes an identifier that is indicative of the sensor from which the signal is sent. Brune et al disclose an analogous measuring system comprising sensors 2 that transmit a signal including an identifier code that is indicative of the sensor from which the signal is sent (Col.5: 49-61). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the signals sent from the implanted sensors of Schulman et al an identifier code as taught by Brune to effectively differentiate the particular sensor from which each signal was sent.

7. Schulman et al and Brune also do not expressly disclose the receiver determines a location for each sensor within an esophagus based on the identifier, and monitors the physiological parameter indicative of gastroesophageal reflux as a function of distance based on the signals and the locations. Ishikawa et al teach that the location of a plurality of implanted sensors is determined based on an identifier (Col.4: 35-39; Col.5: 25-30) to allow proper determination of a desired process based on the known location. Scarantino et al teach that a plurality of implanted sensors are positioned at different locations to gain more regional specific

information regarding the site of placement (Col.25: 1-33), such as when measuring pH for gastrointestinal applications (Col.4: 30; Col.8: 53-66). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Schulman et al and Brune such that the receiver determines a location for each sensor such as within an esophagus based on the identifier, and monitors the physiological parameter indicative of gastroesophageal reflux as a function of distance based on the signals and the locations, as taught by Ishikawa et al and Scarantino et al, to enhance the invention by taking into account the effect of location/distance of the sensor for the measurement of the physiological parameter indicative of gastroesophageal reflux and thus provide a more specific determination of such.

8. In regards to **Claim 51**, Schulman et al disclose the plurality of sensors includes a pH monitor (Col.4: 64) but do not explicitly disclose said sensors including an RF transmitter. Brune teaches the use of an RF transmitter 9,10 to transmit the signals from an analogous implanted sensor 2 (Col.6: 40-42). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Schulman et al so that the plurality of sensors include an RF monitor as an effective means to transmit the signal information wirelessly.

9. In regards to **Claim 52**, Schulman et al in combination with Brune disclose the plurality of sensors above including pH monitors and RF transmitters to periodically send an RF signal indicative of the pH measured by the pH monitor as explained above but do not explicitly disclose the plurality of sensors each includes a microprocessor that periodically receives a

signal from the pH monitor and induces the RF transmitter to periodically send an RF signal indicative of the pH measured by the pH monitor. Brune teaches analogous implanted sensor 2 includes a microprocessor 7 that periodically receives a signal from the sensor and induces the RF transmitter to periodically send an RF signal indicative of the sensor (Col.6: 22-42).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the plurality of sensors of Schulman et al as modified by Brune to include a microprocessor that periodically receives a signal from the pH monitor and induces the RF transmitter to periodically send an RF signal indicative of the pH measured by the pH monitor as an effective means to periodically transmit the pH information signal.

10. In regard to **Claims 53-54**, Schulman et al in combination with Brune disclose the plurality of sensors each with a microprocessor above but do not explicitly disclose the microprocessor enables the pH monitor during a first interval and then disables the pH monitor during a second interval, while the RF transmitter is enabled during the second interval and disabled during periods of each cycle other than the second interval. However, Brune does disclose a first interval which is defined as when the microprocessor 7 periodically enables the sensor to obtain a signal and a second interval which is defined as when the RF transmitter 9,10 is enabled to transmit the signal (Col.6: 35-42). Brune also teaches that battery life is conserved by disabling the respective functions i.e. keeping the sensor in sleeping mode until it is necessary to trigger the signals (Col.6: 32-35).

11. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Schulman et al as modified by Brune such that

during the first interval the RF transmitter is disabled and during the second interval the pH monitor is disabled, wherein the disabling occurs when the respective function is not performed, i.e. the pH monitor of the respective sensor is disabled during periods of each cycle other than the first interval and the RF transmitter is disabled during periods of each cycle other than the second interval, as an effective way to enhance the battery life conservation by only enabling the proper function as it is being used and disabling it during all other times.

12. In regards to **Claim 58**, Schulman et al in combination with Brune, Ishikawa et al, and Scarantino et al disclose the receiver monitors a change in pH as a function of distance/location such as from a lower esophageal sphincter as explained above.

13. **Claims 56-57** are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman et al in view of Brune, Ishikawa et al, and Scarantino et al, further in view of Kumar et al (US Pat No. 6416471).

14. Schulman et al in combination with Brune disclose the receiver above but do not disclose the receiver worn by the patient or includes circuitry to sense the position of the patient. Kumar et al disclose an analogous receiver 20 worn by the patient best seen in Figure 1 as well as circuitry to sense a position of the patient (Col.11: 35-41). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the receiver of Schulman et al as modified by Brune, Ishikawa et al, and Scarantino et al, to be worn by the patient and also include circuitry to sense a position of the patient as taught by Kumar et al for ease of transportation and to improve the invention by also providing valuable information

pertaining to the position of the patient respectively, wherein it is then also obvious to one within the art for the receiver to also periodically record the position of the patient for the purpose of record.

Response to Arguments

15. Applicant's arguments with respect to claims 50-52 and 55-58 have been considered but are moot in view of the new ground(s) of rejection.

16. Applicant's arguments regarding Claims 53-54 have been fully considered but they are not persuasive. In regards to Applicant's arguments that the combination of at least Schulman et al and Brune do not disclose the combination of enabling the pH monitor during a first interval and enabling the RF transmitter during a second interval, it is maintained however that Schulman et al and Brune make obvious such enabling and disabling of a first interval, defined as when the microprocessor 7 periodically enables the sensor to obtain a signal and a second interval, defined as when the RF transmitter 9,10 is enabled to transmit the signal (Col.6: 35-42). Because Brune also already discloses that battery life is conserved by disabling the respective functions i.e. keeping the sensor in sleeping mode until it is necessary to trigger the signals (Col.6: 32-35), it would have been obvious to one of ordinary skill in the art to modify Schulman et al and Brune such that each interval is enabled and disabled separately, to further conserve battery life.

17. It is noted that for a proper §103 rejection, "There are three possible sources for a motivation to combine references: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art." In re Rouffet, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998). "There is no requirement that an

"express, written motivation to combine must appear in prior art references before a finding of obviousness." See *Ruiz v. A.B. Chance Co.*, 357 F.3d 1270, 1276, 69 USPQ2d 1686, 1690 (Fed. Cir. 2004). For example, motivation to combine prior art references may exist in the nature of the problem to be solved (*Ruiz* at 1276, 69 USPQ2d at 1690) or the knowledge of one of ordinary skill in the art (*National Steel Car v. Canadian Pacific Railway Ltd.*, 357 F.3d 1319, 1338, 69 USPQ2d 1641, 1656 (Fed. Cir. 2004))." See MPEP 2143.01. The test for combining references is what the combination of disclosures taken as a whole would suggest to one of ordinary skill in the art. *In re McLaughlin*, 170 USPQ 209 (CCPA 1971). References are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures. *In re Bozek*, 163 USPQ 545 (CCPA) 1969.

18. Furthermore, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen Nguyen whose telephone number is 571-272-8340. The examiner can normally be reached on Monday - Friday, 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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